

## **II. REMARKS**

By the present amendment, independent claims 36 and 37 have been amended, and new claims 38-47 have been added. Specifically, claims 36 and 37 have been amended to recite “the bar is a straight solid bar made of metal” as supported on page 5, lines 23-25, and by Figure 4 of Applicant’s disclosure as originally filed.

New independent claims 38 and 39 incorporate subject matter of independent claims 21 and 31, respectively, and recite “mounting the bar of the stud in a fistula formed in a wearer’s tongue or in the wearer’s lip so that the first end member and the second end member hold the stud in the fistula” as supported on page 2, lines 3-8, and on page 4, lines 20-22, and recite “the substance is dispensed by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva” as supported on page 5, lines 10-12, of Applicant’s specification as originally filed. New claims 40 and 41 depend on claims 38 and 39, respectively, and additionally recite “wherein an insert is disposed in the means for dispensing a substance” as supported on page 5, lines 8-12, of Applicant’s specification as originally filed.

New claims 42 and 43 depend on claims 22 and 31, respectively, and additionally recite “wherein the substance has a form selected from the group consisting of a solid crystallized form, a gel, a foam and a tablet form” as supported on page 6, lines 10-13, of Applicant’s specification as originally filed.

New independent claims 44 and 45 incorporate the subject matter of independent claims 21 and 31, respectively, and recite “mounting the bar of the stud in a fistula formed in a wearer’s tongue or in the wearer’s lip so that the first end member and the second end member hold the stud in the fistula” as supported on page 2, lines 3-8, and on page 4, lines 20-22, and recites “the substance is dispensed by leaching the substance from the stud into the wearer’s mouth over time in the wearer’s saliva” as supported on page 3, lines 2-7, of Applicant’s specification as originally filed.

New claims 46 and 47 depend on claims 22 and 31, respectively, and additionally recite “wherein the bar is a solid bar and the means for dispensing a substance is formed in the second end

member” as supported on page 9, lines 16-21, of Applicant’s specification as originally filed.

The present amendment adds no new matter to the above-captioned application.

**A. The Invention**

The present invention pertains broadly to a method for dispensing a substance into a mouth, such as could be used to dispense a breath freshener, a flavoring agent, a medication, or a combination of these substances. In one embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 21. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 31. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 36. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 37. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 38. In yet another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 39. In another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, is provided comprising the steps recited in claim 44. In still another embodiment of the present invention, a method of dispensing a substance into a mouth, wherein the substance is a medication, is provided comprising the steps recited in claim 45.

Various other embodiments, in accordance with the present invention, are recited in the

dependent claims. All of the embodiments, in accordance with the present invention, provide the advantage of using a “mouth and tongue stud” to dispense a substance into a wearer’s mouth. As would be understood by a person of ordinary skill in the art, a “mouth and tongue stud” is a particular kind of jewelry having features allowing it to be disposed in the mouth of a wearer.

**B. The Rejection**

Claims 21-31, 36 and 37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Denney et al. (U.S. Patent 6,047,209) in view of Edwards (U.S. Patent 4,943,274). Claims 21-31, 36 and 37 also stand rejected under 35 U.S.C. § 103(a) as unpatentable over Denney et al. (U.S. Patent 6,047,209, hereafter, the “Denney Patent”) in view of Edwards (U.S. Patent 4,943,274, hereafter the “Edwards Patent”), and further in view of Taylor et al. (U.S. Patent 5,090,903, hereafter the “Taylor Patent”).

I respectfully traverse the rejection and request reconsideration of the application for the following reasons.

**C. Applicant’s Arguments**

A prima facie case of obviousness requires a showing that the scope and content of the prior art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation, or other reason, to combine the references to produce the claimed invention. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1742 (2007); In re Oetiker, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). A proper rejection under Section 103 also requires showing (1) that the prior art would have suggested to a person of ordinary skill in the art that they should make the claimed device or carry out the claimed process, (2) that the prior art would have revealed to a person of ordinary skill in the art that in so making or doing, there would have been a reasonable expectation of success, and (3) both the suggestion and the reasonable expectation of success must be found in the prior art and not in the applicants’ disclosure. In re Vaeck, 20 U.S.P.Q.2d 1438, 1442

(Fed. Cir. 1991). An obviousness analysis, however, is not a rigid formulaic analysis, but is a flexible determination grounded in the facts of the case. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1739 (2007). Indeed, the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007).

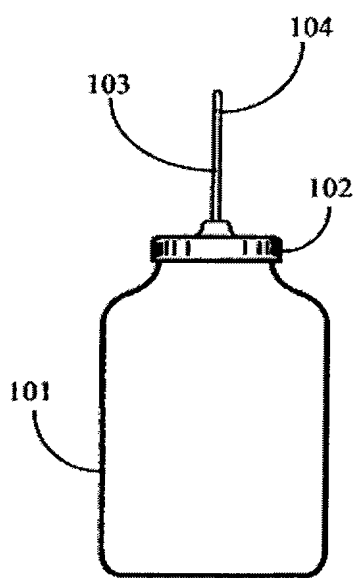
In the present case, the Examiner has failed to establish a prima facie case of obviousness against the presently claimed invention because neither the Denny Patent, the Edwards Patent, nor the Taylor Patent teaches, or even suggests, (i) a “mouth and tongue stud” and (ii) “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37. The Examiner’s Section 103 rejection is also untenable and must be withdrawn because the combination of the Denny Patent, the Edwards Patent and the Taylor Patent fails to teach, or even suggest, a “method for dispensing a substance into a mouth” that includes the step of (iii) “providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud... wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar” and wherein “the first end member removably attaches to the one end of the bar” and “mounting the bar of the stud in a fistula...” as recited in independent claims 21, 31, 36 and 37.

The Examiner has also failed to establish a prima facie case of obviousness against the claims of the above-captioned application because the Examiner has established no teaching, suggestion, motivation, or other legitimate reason, to justify combining the disclosures of the Denny Patent, the Edwards Patent and the Taylor Patent.

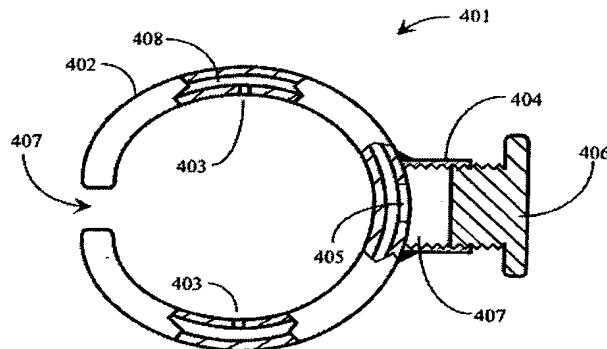
**i. The Denny Patent**

U.S. Patent 6,047,209, the Denny Patent, discloses a “method and apparatus for maintenance of pierced orifices” for injecting fluid into a pierced body orifice (See Abstract). The Denny Patent does not teach or even suggest, a “mouth and tongue stud” as recited by independent claims 21, 31,

36 and 37. On the contrary, the Denny Patent discloses a “needle” (103) as shown in Figure 3, and a “ring” (401) as shown in Figure 4. Both of these Figures are reproduced below.



**Fig. 1**



**Fig. 4**

A person of ordinary skill in the art would immediately realize that neither the apparatus of Figure 1 nor of Figure 4 is a “mouth and tongue stud” for many reasons. One reason is because neither needle (103) nor ring (401) includes structure that would allow them to remain in the tongue or other piercing that involves the mouth. Another reason is that the apparatus shown in Figure 3 is a ring and not a “stud.” Yet another reason is that the apparatus shown in Figure 1 or Figure 2 has a needle (103) or (201) attached to a squeeze bottle (101) and is not a “tongue and mouth stud.” Likewise, the ring (401) includes a needle (402) and is also not a “tongue and mouth stud.” As conceded by the Examiner (Office Action, dated August 3, 2007, at 4, lines 14-16), the Denny Patent does not teach, or suggest, “the substance comprises a breath freshener” as recited by claim 22 and “the substance comprises a flavoring agent” as recited by claim 23. Other reasons why the Denny Patent does not teach, or even suggest, a “mouth and tongue stud” are as follows.

#### **The Denny Patent Discloses Syringes**

A person of ordinary skill in the art would immediately recognize that the device shown in

Figure 1 of the Denny Patent is a “syringe.” As defined by THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1306 (1979), filed herewith, a “syringe” is “a device used to inject fluids into the body or draw them from it.” THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, at 1306, shows a picture of a syringe that employs a plunger to inject fluids through a needle, as would be immediately recognized by a person of ordinary skill in the art. The device shown in Figure 1 of Denny, which is an “injection system,” employs a plastic squeeze bottle in place of the plunger to inject fluids into a fistula (302) formed in a body part (301) as shown in Figure 3 (See also Denny Patent, col. 2, lines 32-44, and col. 3, line 66, to col. 4, line 13). A person of ordinary skill in the art would further recognize that the “injection system” of Figure 1 (and of Figure 2) of the Denny Patent is a type of syringe known as a “bulb syringe” in which the flexible squeeze bottle is the “bulb.”

The device shown in Figure 4 is another syringe as would be instantly recognized by a person of ordinary skill in the art. Specifically, the ring (401) includes a body (402), which is nothing more than a needle curved into the shape of a ring (See Figure 4). At the middle of the needle (402) there is provided a reservoir (407) in base (404), wherein fluid or salve is ejected from the reservoir (407) by turning knob (406) threaded into base (404) so that fluid or salve is manually dispersed (col. 4, line 66, to col. 5, line 2). A person of ordinary skill in the art would instantly realize that the knob (406) moves by turning so as to push fluid from the reservoir (407) into the needle (402) in much the same way that the plunger of the syringe shown at 1306 of THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (1979) is used to push fluid out of a conventional syringe.

In view of the above, it is clear that the Denny Patent does not teach, or suggest, (i) “providing a mouth and tongue stud including means for dispensing a substance...” as recited in independent claims 21, 31, 36 and 37 of the present application because the Denny Patent discloses various embodiments of syringes. Furthermore, the Denny Patent does not teach, or suggest, (ii) “mounting the bar of the stud in a fistula...” and (iii) “the substance is dispensed into the wearer’s

mouth by dissolving the substance over time in the wearer's saliva" as recited in independent claims 21, 31, 36 and 37.

Those skilled in the art would realize that the mouth is a very active place so jewelry used in the mouth must have appropriate structure for securing it in place; otherwise, the jewelry will fall out of place and be swallowed or aspirated. The production of saliva, which is a lubricant, makes this problem even more acute. A reasonable person skilled in the art would not place the unsecurable needle (103) of the syringe shown in Figure 1 of Denny, or the unsecurable needle (402) of the syringe (401) shown in Figure 4 of Denny, in the mouth of a wearer to maintain a "pierced orifice" because of the aspiration and trauma hazard created by placing unsecurable objects (especially needles of syringes) in the mouth. In other words, the fact that the needle (103), (201) and the ring (401) disclosed by the Denny Patent are constructed as syringes, and do not have structure to secure them in place in a fistula, is strong evidence that each of these devices is not a "mouth and tongue stud" as recited by the independent claims.

#### **The Devices Disclosed by Denny are for External Use Only**

The Denny Patent describes placing the needle (103) in a "pierced orifice" (i.e., a fistula) having an interior (302), and the use of hydrogen peroxide, soap and water, and topical antibiotics would reasonably suggest to one of ordinary skill in the art that Denney discloses a device for application to "any pierced orifice on the body" (col. 3, lines 28-54, and Figure 3), which would not include piercings in the body such as those involving the mouth.

More specifically, the Denny Patent states at col. 1, lines 28-65, that

"[t]he current method of cleaning a pierced orifice is to swab newly pierced areas twice a day with antiseptic hydrogen peroxide, then dab on an antibiotic ointment such as Polysporin. After about a week, soap and water is thought to be sufficient....

With these current methods of piercing maintenance, it is recommended that a person remove earrings at the first sign of redness, swelling, crusting or oozing, and wash effected areas with soap and water....

The prior art practice does not effectively reduce infection within the pierced orifice, only around it. The only method suggested for cleaning or disinfecting the inside of a newly pierced orifice is the application of substances on the jewelry using a cotton swab and then rotating the ring or bar to attempt to get the substance into the inside of the orifice. The

problem with this method is that the human skin often acts as a squeegee, thereby preventing the substance from effectively entering the interior of the pierced orifice” (emphasis added).

A person of ordinary skill in the art would immediately understand from Denny’s disclosure that the injection devices disclosed by the Denny Patent are designed to inject substances into a “pierced orifice” (i.e., fistula) created in the skin (not the mouth) of a human subject. In further support of this interpretation of the Denny Patent, Applicant directs the Examiner’s attention to Barton Schmidt, *Your Child’s Health: the Patents Guide to Symptoms, Emergencies, Common Illnesses, Behavior and School Problems*, (Rev. Ed. 1991), 77-78, 80-82 and 524-527 (of record, hereafter the “Schmidt Text”). Specifically, the Schmidt Text, at 524-525, discloses that “[t]he most common complication of pierced ears [a skin piercing] is a bacterial infection of the channel.” The Schmidt Text further discloses, at 525-526, that home care for mild ear piercing infection involves “cleans[ing the earring post] with rubbing alcohol. Apply Bacitracin ointment...to the post and reinsert it. Continue the antibiotic ointment for 2 days beyond the time the infection seems cleared.” The Schmidt Text is consistent with the disclosure of the Denny Patent (See, e.g., Denny Patent, col. 1, lines 17-22), which also discloses using antibiotic ointment to treat skin piercings and other external piercings. Both documents disclose that topical antibiotics are a treatment for skin piercings. Filed herewith as “Exhibit A” is a photocopy of the front and back faces of a Bacitracin ointment tube. As evident from Exhibit A, Bacitracin is “for external use only” and the tube suggests “seeking professional assistance or contact a Poison Control Center” if the ointment is accidentally ingested. A person of ordinary skill in the art would know that Polysporin, another topical antibiotic ointment, is also “for external use only” and is not to be used in the mouth or ingested.

In sum, the Denny Patent, the Schmidt Text and Exhibit A all demonstrate that topical antibiotic ointment is a treatment for infected piercing channels (i.e., a “piercing orifice”) of the skin. The Examiner has adduced no evidence to rebut these facts. While the Examiner contends that the Denny Patent discloses “mounting the stud in a fistula of a wearer’s tongue or in the wearer’s lip,” and contends that support for this contention is found in the Abstract and in Figure 3 of the Denny Patent (Office Action, dated August 3, 2007, at 2, lines 19-20), Applicant disagrees. Figure 3 of the



Denny Patent is reproduced below to show that there is no “end member.” However, Figure 3 of the Denny Patent also shows needle (103) inserted into a “pierced orifice” (302), i.e., a fistula, formed in a “body part” (301), (col. 4, lines 25-40). To the extent that the Examiner contends the Denny Patent discloses the “body part” (301) is a tongue or lip, Applicant objects. The Denny Patent does not identify the “body part” and, as discussed above, the subject matter of the Denny Patent is directed to treating infections of external skin piercings. The Denny Patent does not teach, or suggest, any method for treating internal oral piercings, such as those involving the tongue or inner lip.

To the extent that the Examiner contends the phrase “pierced body orifice” pertains to the mouth of a wearer, Applicant objects. As plainly illustrated in Figure 3 of the Denny Patent (See also, Denny Patent, at col. 4, lines 25-40), the “pierced orifice” (302) pertains to the piercing channel or fistula formed in the “body part” (301) and does not refer to the mouth of the wearer.

The Federal Circuit has ruled that the United States Patent and Trademark Office (USPTO) must give a fair reading to what a reference teaches as a whole. In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In the present case, the Examiner has not given a fair reading to the subject matter the Denny Patent teaches as a whole. Specifically, there is nothing in the Denny Patent that teaches, or even suggests, that the method disclosed by Denny would apply to intraoral piercings, and the common sense of a person of ordinary skill in the art would lead one away from using any of the devices (i.e., the needle and ring syringes) disclosed by Denny in the manner claimed by the present invention to dispense a substance into a wearer’s mouth.

#### **Denny Does not Disclose Any “End Members”**

These are not the only deficiencies in the teachings of the Denny Patent demonstrating that Denny does not teach a “mouth and tongue stud” as recited in the claims. The Denny Patent also does not teach, or suggest, that (iv) “the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar” and (b) “the first end member removably attaches to the one end of the bar” as recited in independent claims

21, 31, 36 and 36.

As shown in Figure 1 of the Denny Patent, the needle (103) does not have both a “first end member” and a “second end member” as recited in claims 21, 31, 36 and 37. This fact is plainly evident from Figure 3 of the Denny Patent, which is reproduced below.

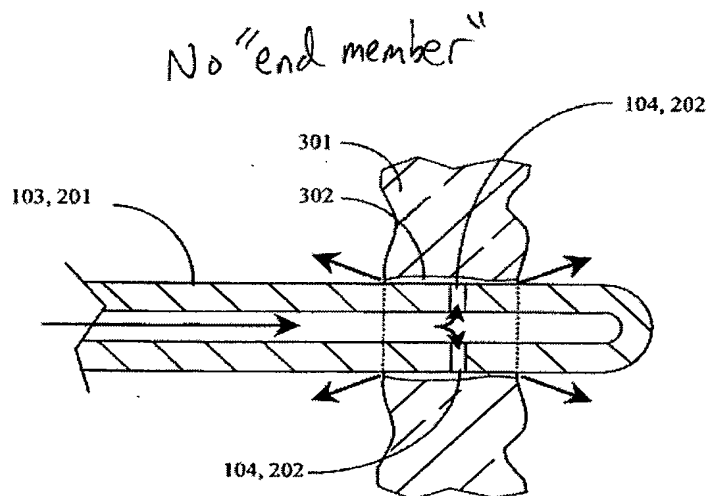


Figure 3 (modified) of the Denny Patent

While the Examiner contends that that cap (102) is an “end member” (Office Action, dated August 3, 2007, at 2, lines 18-19), a person of ordinary skill in the art would instantly realize that cap (102) and needle (103) is not a device intended for use in the mouth of a wearer. As admitted by the Examiner (Office Action, dated August 3, 2007, at 3, lines 5-7), the Denny Patent does not teach, or suggest, a “second end member” as recited in independent claims 21, 31, 36 and 37.

For all of the above reasons, Applicant has pointed out and clearly shown that the Denny Patent does not teach, or even suggest, devices that are mouth and tongue studs, or that could even be reasonably construed to be mouth and tongue studs. In fact, a person of ordinary skill in the art would instantly realize, for all of the above reasons, that the devices disclosed by Denny cannot reasonably be used in the oral cavity of a wearer. Instead, a person of ordinary skill in the art would understand that the Denny Patent discloses at least two syringe embodiments employing needles for inserting into the fistula of a skin piercing. Therefore, the Denny Patent cannot teach, or even suggest, the subject matter of claims 21, 31, 36 and 37 because the patent does not disclose the step

of “providing a mouth and tongue stud including a means for dispensing a substance.”

**Denny does not Disclose Using Saliva to Dispense a Substance**

The Denny Patent also does not teach, or suggest, that “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by claims 21, 31, 36 and 37. As admitted by the Examiner, the Denny Patent discloses that the substance is disposed “by injecting the substance into the piercing” (Office Action, dated March 8, 2007, at 4, lines 11-12; Office Action, June 14, 2006, at 4, lines 21-23). The Examiner repeatedly admits that the Denny Patent “fails to disclose that the substance is disposed by dissolving the substance over time in the wearer’s saliva” (Office Action, dated August 3, 2007, at 4, lines 4-5; Office Action, dated March 8, 2007, at 3, lines 12-13).

Despite these repeated admissions, the Examiner now contends that it would have been obvious for the substance, after it has been injected into the piercing, to also dissolve over time in the wearer’s saliva once in the mouth and that such a condition would meet the claimed limitation (Office Action, dated March 8, 2007, at 4, lines 13-18; and Office Action, dated June 14, 2006, at 4, line 22, to at 5, line 3). The Examiner erroneously contends

“it would have been obvious to one having ordinary skill in the art at the time of applicant’s invention that the substance is dispensed as it travels out of the piercing and it will be dissolved over time in the wearer’s saliva after being injected into the piercing since time is needed to complete (sic) dissolve the substance since the substance fails to be dissolved instantly upon application” (Office Action, dated August 3, 2007, at 4, lines 6-10, emphasis added).

The Examiner’s contention is based on a misconstruction of the claimed invention and is erroneous for the following reasons.

While the Examiner is encouraged to give Applicant’s claims the broadest reasonable interpretation consistent with the specification, In re Hyatt, 54 U.S.P.Q.2d 1664, 1667 (Fed. Cir. 2000), the Examiner is not free to give an unreasonable interpretation to the claimed invention. In this case, the Examiner has not given a reasonable interpretation to the invention as claimed.

Specifically, independent claims 21, 31, 36 and 37 recite “the substance is dispensed...by dissolving the substance over time in the wearer’s saliva.” There are many definitions of the word “dispense” and the Examiner is encouraged to give a broad interpretation of this term. Because Applicant’s specification does not explicitly define the term “dispense,” it should be given its ordinary meaning as would be understood by a person of ordinary skill in the art. Phillips v. AWH Corporation, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005)(*en banc*). Furthermore, encyclopedias and dictionaries may be consulted to establish what the ordinary meaning of a claim term may be. Phillips v. AWH Corporation, 415 F.3d at 1318. THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 379 (1979), filed herewith, gives a definition for the word “dispense,” which is “[t]o deal out or distribute in parts or portions.” Thus, a broad reasonable interpretation of the claimed phrase “is dispensed...by dissolving the substance over time in the wearer’s saliva” is that the substance is “dealt out or distributed in parts or portions by dissolving the substance over time in the wearer’s saliva.” This broad interpretation is consistent with Applicant’s original specification, at 5, lines 1-6.

However, there is more to the language of the independent claims. The full phrase, recited by claims 21, 31, 36 and 37, is “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva.” Thus, the broadest reasonable interpretation of the claims consistent with Applicant’s specification is that the substance is “dealt out or distributed in parts or portions into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva.” Because Applicant’s specification does not explicitly define the term “mouth,” it should be given its broadest ordinary meaning as would be understood by a person of ordinary skill in the art, and consultation to encyclopedias and dictionaries may establish what the ordinary meaning of the term may be. Phillips v. AWH Corporation, 415 F.3d at 1316 and 1318. THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 379 (1979), filed herewith, gives multiple definitions for the word “mouth,” including

- a.** The body opening through which an animal takes in food; the oral cavity.
- b.** The system of related organs including the lips, teeth, tongue, and associated parts,

with which food is chewed and swallowed and sounds and speech are articulated.”

In view of the above, a broad reasonable interpretation of the claimed phrase “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” is that the substance is “dealt out or distributed in parts or portions into the wearer’s mouth, which includes any of the tongue, lips, oral cavity, and associated parts, by dissolving the substance over time in the wearer’s saliva.” This broad interpretation is consistent with Applicant’s original specification, at 5, lines 1-6. A person of ordinary skill in the art would instantly appreciate that the claimed invention passively dispenses the substance into the mouth by dissolving it using the wearer’s saliva. A person of ordinary skill in the art would also instantly appreciate that Denny discloses actively dispensing a substance by injection. A person of ordinary skill in the art, realizing that the claimed invention pertains to passive dispensing of the substance into the mouth using saliva, would understand that it is distinguished from Denny’s active injection process.

The Examiner erroneously reads additional limitations into, and/or grossly misconstrues, the language of Applicant’s claims. Specifically, the Examiner contends that the Denny Patent discloses “[t]he substance is disposed into the wearer’s mouth by injecting the substance into the piercing [302]” (Office Action, dated August 3, 2007, at 4, lines 3-4). Applicant agrees with the Examiner that Denny discloses injecting a medication into a piercing (302). However, Applicant disagrees that Denny discloses injecting medication into a piercing located in the mouth of a wearer. Assuming, *arguendo*, that Denny teaches injecting medication into a piercing located in the mouth of a wearer (which, of course, is a wholly invalid assumption), the Examiner’s argument still fails for the following reasons.

Specifically, the Examiner contends that once the medication is injected into the piercing (302), it will then be “dispensed as it travels out of the piercing [302] and it will be dissolved over time in the wearer’s saliva after being injected into the piercing [302] since time is needed to complete dissolve the substance” (Office Action, dated August 3, 2007, at 4, lines 6-10, emphasis added). In other words, the Examiner argues that after medication is injected from Denny’s device

into a pierced orifice, it then is dispensed from the pierced orifice into the wearer's mouth by dissolving the medication in saliva. However, the pierced orifice is not part of Denny's device but is a part of the wearer's mouth.

The Examiner's argument wherein medication leaving the pierced orifice would meet the language of the claimed invention is untenable because once the substance has been injected into the piercing (302), which the Examiner contends is in the tongue or lip of a wearer, it has already been "dispensed" by injection as admitted by the Examiner. Therefore, once the substance has been injected into the piercing it has been "dispensed" as that term is used in the present claims. Any subsequent travel of the substance once it has been "dispensed" into the wearer's mouth is not relevant to the claimed invention.

This point is even more clear in view of the claim phrase "the substance is dispensed into the wearer's mouth" as recited by independent claims 21, 31, 36 and 37. This phrase, when given its broadest reasonable interpretation, means that the "substance" has been "dispensed" once the "substance" has traveled "to the inside of" or "so as to be in or within" the wearer's mouth (See, e.g., THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 686 (1979), filed herewith, which gives multiple definitions for the word "into"). Once the claims have been given their broadest reasonable interpretation consistent with Applicant's specification, it is clear that the Denny Patent's syringe devices dispense medication by injection and not by "dissolving the substance over time in the wearer's saliva." Any subsequent or secondary movement of the medication from the pierced orifice to another part of the mouth would not meet the "dispensing" limitation as claimed for the following reasons.

The Examiner contends that after the substance has been injected into the piercing of the mouth or lip, it would then be "dispensed as it travels out of the piercing" (Office Action, dated August 3, 2007, at 4, lines 3-10). As discussed above, the tongue and lip are parts of the mouth so that a piercing of the tongue or lip is also a part of the mouth. Therefore, once the medication disclosed by Denny has been injected into the piercing of the tongue or lip, it has been "dispensed

into the wearer's mouth" given the broadest reasonable interpretation of the claims. Therefore, as admitted by the Examiner, Denny's medication would be "dispensed into the wearer's mouth" by injection and not "by dissolving the substance over time in the wearer's saliva."

While the Examiner contends that Denny discloses "[t]he substance is disposed into the wearer's mouth by injecting the substance into the piercing" (Office Action, dated August 3, 2007, at 3-4, emphasis added), the Examiner must concede that Denny discloses the substance is dispensed into the piercing by injecting the substance into the piercing so that if the piercing is in the tongue or lip (as the Examiner contends), then the substance has been dispensed into the wearer's mouth by injection. The Examiner's contention that the "substance is dispensed as it travels out of the piercing," and therefore meets the limitation "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva," is plainly flawed because how can the substance be "dispensed into the wearer's mouth" by moving it from a tongue or lip piercing (which is part of the mouth) to the oral cavity (which is another part of the mouth)? The answer is that the substance cannot be "dispensed into the wearer's mouth" by moving it from one part of the mouth to another. Instead, the substance is "dispensed into the wearer's mouth" by moving it from the "tongue and mouth stud" to any part of the mouth.

In sum, the phrase "the substance is dispensed into the wearer's mouth by dissolving the substance over time in the wearer's saliva" recited by claims 21, 31, 36 and 37, when given its broadest reasonable interpretation, means that (a) the "substance" is (b) "dispensed into the wearer's mouth" by (c) "dissolving the substance over time in the wearer's saliva." The Examiner's contention that the claimed invention reads on a method wherein (a) the "substance" is (b) injected into the mouth (i.e., a piercing located in the tongue or lip), and (c) the substance once in the mouth piercing is (d) further "dispensed" into other portions of the mouth such as the oral cavity by (e) "dissolving the substance over time in the wearer's saliva" is not a reasonable interpretation of Applicant's claimed invention. As discussed above, once the substance has been "dispensed into the wearer's mouth" by injection it has already been dispensed from Denny's device. Consequently, it

cannot be further “dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” by moving the substance from the pierced orifice to another part of the mouth as the Examiner contends.

For all of the above reasons, the Examiner’s contention that the Denny Patent discloses “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” is untenable. For all of the above reasons, the Examiner’s argument is flawed because it depends on an unreasonable interpretation of the claimed invention and on an unreasonable interpretation of the disclosure of the Denny Patent. For all of the above reasons, the Denny Patent does not teach, or suggest, “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37.

#### **Summation of the Deficiencies of the Denny Patent**

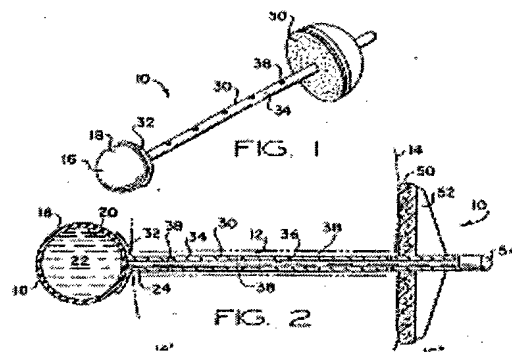
In sum, the Denny Patent does not teach, or even suggest, (i) a “mouth and tongue stud” as recited in independent claims 21, 31, 36 and 37. The Denny Patent also does not teach, or suggest, (ii) “the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar” and that (iii) “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37 of the above-captioned application. Furthermore, the Denny Patent does not teach, or even suggest, (iv) “mounting the bar of the stud in a fistula formed in a wearer’s tongue or in the wearer’s lip” as recited by independent claims 21 and 31 and, (v) “mounting the bar of the stud in a fistula in a part of wearer’s mouth” as recited by independent claims 36 and 37 of the present application. The Denny Patent also does not teach, or suggest, (vi) “the substance comprises a breath freshener” as recited by claim 22 and (vii) “the substance comprises a flavoring agent” as recited by claim 23, (viii) “an insert is disposed in the means for dispensing a substance” as recited by claims 40 and 41, (ix) “the substance has a form selected from



the group consisting of a solid crystallized form, a gel, a foam and a tablet form” as recited by claims 42 and 43, and (x) “the bar is a solid bar and the means for dispensing a substance is formed in the second end member” as recited by claims 46 and 47. The Denny Patent also does not teach, or suggest, (xi) “the bar is a straight solid bar made of metal” as recited by independent claims 36 and 37.

## ii. The Edwards Patent

The Edwards Patent discloses an “apparatus for applying earlobe medicine” which is inserted into the earlobe (See Abstract). This ear apparatus is not a mouth and tongue stud and there is no teaching, or suggestion, that the apparatus would be used in the oral cavity. One skilled in the art would recognize that the apparatus (10) as shown in Figures 1 and 2 does not have the features of a mouth and tongue stud and is not suitable for use in the mouth. For convenience, Figures 1 and 2 of the Edwards Patent are reproduced below because they illustrate the many deficiencies of the apparatus (10) disclosed by Edwards.



In particular, apparatus (10) has a relatively pointed protruding “end” (54). Mouth and tongue studs do not have points such as “end” (54) because such a pointed structure would seriously damage the mucosal surfaces in the mouth. Apparatus (10) disclosed by the Edwards Patent also has a felt pad (50) as a backing for retainer (52). Mouth and tongue studs, unlike earrings and devices for inserting into the earlobe, are restricted to certain non-toxic suitable materials for putting into the mouth. Felt is not a suitable material for the mouth. In the wet environment of the mouth, the felt

would quickly degrade, break apart, and present an aspiration hazard. Furthermore, retainer (52) as shown in Figure 2 is only held in place by friction. Mouth and tongue studs cannot use simple friction retainers because the connection between the retainer and the rest of the apparatus is not robust. The mouth is a very active place with eating, drinking, speaking, and facial expressions going on. As a result, mouth and tongue studs must be securely inserted into the tongue or lip. As is commonly known by those skilled in the art, if a mouth and tongue stud falls out of its piercing and into the mouth there is a serious potential for harm from aspirating the stud or its component parts into the lungs or from choking. Generally, a threaded connection, or a weld and the like, is used to attach an “end member” of the mouth and tongue stud to the bar because this is a suitably secure connection. Friction retainers or clasps are not used.

Apparatus (10) disclosed by Edwards also has a resilient housing (16) made of neoprene, polypropylene or polyethylene so that housing (16) is squeezable (col. 2, lines 15-25, and col. 3, lines 3-10). Such a squeezable housing is unsuitable for use as a structure of a mouth and tongue stud for several reasons. First, housing (16), being compressible, would defeat one of the purposes of a mouth and tongue stud, being to enhance sexual activity. Second, the housing (16) could not hold the “antibiotic gel, petroleum or aloe-based ointments” (col. 2, lines 22-24) effectively because, once the apparatus (10) was inside the mouth, the housing would be compressed by some portion of the mouth. Thus, once in the mouth, housing (16) would not be an effective reservoir.

Furthermore, a person of ordinary skill in the art would immediately realize that the apparatus (10) disclosed by the Edwards Patent is a syringe. Specifically, apparatus (10) includes a tubular conduit (30), i.e., a needle, and a squeezable resilient housing or reservoir (16), wherein the apparatus (10) is operated to force pressurized medicament (22) through the conduit (30) and into an ear piercing when the reservoir (16) is squeezed (col. 3, lines 3-10). More specifically, a person of ordinary skill in the art would immediately realize that apparatus (10) is a “bulb” syringe wherein the reservoir (16) is the bulb.

Given the fact that the apparatus (10) disclosed by Edwards has a different structure from the

present invention, is not a mouth and tongue stud, cannot function as a mouth and tongue stud, and has no parts that would be suitable for use by a mouth and tongue stud, it is clear that any rejection under 35 U.S.C. §§ 102(b) and 103(a) relying upon the Edwards reference would be untenable. For all of the above reasons, a person of ordinary skill in the art would also realize that the apparatus (10) is a syringe that is inserted into an earlobe piercing (i.e., a skin piercing), and that it would be contrary to the common sense of a person of ordinary skill in the art to employ the apparatus (10) in the mouth of a wearer.

As conceded by the Examiner (Office Action, dated August 3, 2007, at 4, lines 14-16), the Edwards Patent does not teach, or suggest, “the substance comprises a breath freshener” as recited by claim 22 and “the substance comprises a flavoring agent” as recited by claim 23.

In sum, the Edwards Patent does not teach, or even suggest, (i) “providing a mouth and tongue stud...,” and (ii) “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37. The Edwards Patent also does not teach, or suggest, (iii) “mounting the bar of the stud in a fistula formed in a wearer’s tongue or in the wearer’s lip” as recited by independent claims 21 and 31 and, (iv) “mounting the bar of the stud in a fistula in a part of wearer’s mouth” as recited by independent claims 36 and 37 of the present application. The Edwards Patent also does not teach, or suggest, (v) “the substance comprises a breath freshener” as recited by claim 22 and (vi) “the substance comprises a flavoring agent” as recited by claim 23, (vii) “an insert is disposed in the means for dispensing a substance” as recited by claims 40 and 41, (viii) “the substance has a form selected from the group consisting of a solid crystallized form, a gel, a foam and a tablet form” as recited by claims 42 and 43, and (ix) “the bar is a solid bar and the means for dispensing a substance is formed in the second end member” as recited by claims 46 and 47. The Edwards Patent also does not teach, or suggest, (x) “the bar is a straight solid bar made of metal” as recited by independent claims 36 and 37.

### **iii. The Taylor Patent**

The Taylor Patent discloses a “dental prosthesis with controlled fluid dispensing means,” as shown in Figures 2 and 3, wherein the dental prosthesis is a bridge (11) having an interior cavity (19) with a plurality of chambers (21), (22) and (23), (See Abstract of the Taylor Patent). The Taylor Patent discloses that a first duct (27) communicates between the chamber (21) and the inner face of tooth (12) for dispensing liquid from the chamber (21) into the mouth and that a second passageway (28) communicates between chamber (22) and the outer face of the tooth (12) to provide venting of the cavity so that liquid can be displaced progressively with air as it is dispensed into the mouth (col. 3, lines 54-62). The Taylor Patent discloses that the liquid (29) can be a medication or a breath freshener (col. 3, lines 62-65).

In sum, the Taylor Patent discloses a dental implant. The Taylor Patent does not teach, or even suggest, (i) “providing a mouth and tongue stud...,” (ii) “mounting the bar of the stud in a fistula...,” and (iii) “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37.

#### **iv. Summary of the Disclosures**

The Denny Patent discloses two syringe embodiments including a needle (103) attached to a bottle (101), wherein squeezing the bottle causes fluid or salve to be injected from the needle (103) into a pierced orifice (i.e., a fistula) formed in skin. In a second syringe embodiment, a ring (401) with a base (404) disposed in the middle of the ring body (402) is provided with a knob (406) that, when turned, causes fluid or salve in reservoir (401) to be injected from body (402) into the pierced orifice (i.e., a fistula) formed in skin. The Denny Patent does not teach, or suggest, a “mouth and tongue stud” in accordance with the presently claimed invention. The Denny Patent also does not teach, or suggest, employing either the needle or the ring devices intraorally, and the common sense of a person of ordinary skill in the art would discourage the deployment of a syringe in the mouth of a user in the manner claimed for a “mouth and tongue stud” of the present invention.

In sum, the Denny Patent does not teach, or even suggest, (i) “a method for dispensing a

substance into a mouth,” (ii) “providing a mouth and tongue stud including a means for dispensing a substance,” (iii) “the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar,” and (iv) “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37. The Denny Patent also does not teach, or suggest, (v) “mounting the bar of the stud in a fistula formed in a wearer’s tongue or in the wearer’s lip” as recited by independent claims 21 and 31, and (vi) “mounting the bar of the stud in a fistula formed in a part of a wearer’s mouth” as recited by independent claims 26 and 37.

The Edwards Patent discloses an apparatus for applying earlobe medicine. It does not teach, or suggest, a “mouth and tongue stud” and it does not teach, or suggest, employing its apparatus in the mouth of a wearer. Furthermore, the apparatus disclosed by the Edwards Patent is a syringe, which a person of ordinary skill in the art would not mount in the tongue or lip of a wearer. In fact, the pointed end (54), the friction retainer (52) and the squeezable reservoir are all structures that are unsuitable for use in the mouth of a wearer and that are employed by Edward’s apparatus for applying medication to earlobes.

The Taylor Patent discloses a dental implant that dispenses a breath freshener or a medication using gravity. The Taylor Patent does not teach, or suggest a “mouth and tongue stud” and it does not teach, or suggest, “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37.

In view of the above, the combination of the Denny Patent, the Edwards Patent and the Taylor Patent does not teach, or suggest, a “mouth and tongue stud” as recited in the present claims especially because neither the Denny Patent, the Edwards Patent nor the Taylor Patent teach, or suggest, a “mouth and tongue stud.” Furthermore, the combination of the Denny Patent, the Edwards Patent and the Taylor Patent does not teach, or suggest, “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited by independent claims 21, 31, 36 and 37 because neither the Denny Patent, the Edwards Patent nor the Taylor Patent

disclose this feature.

The combination of the Denny Patent, the Edwards Patent and the Taylor Patent also does not teach, or suggest, “providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud... wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar” and wherein “the first end member removably attaches to the one end of the bar” and “mounting the bar of the stud in a fistula...” as recited in independent claims 21, 31, 36 and 37. Specifically, the common sense of a person of ordinary skill in the art would establish why it is not obvious to attach the friction retainer of Edwards to the needle syringe of Denny and then to employ such a device in the mouth of a wearer as discussed below.

For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against the invention recited by independent claims 21, 31, 26 and 37.

The above reasons also apply to new independent claims 38, 39, 44 and 45. Furthermore, neither the Denny Patent, the Edwards Patent nor the Taylor Patent teach, or suggest, “the substance is dispensed by diffusing the substance from the stud into the wearer’s mouth” as recited by claims 38 and 39, and “the substance is dispensed by leaching” as recited by claims 44 and 45. For all of the above reasons, the Examiner has failed to establish a prima facie case of obviousness against the invention recited by independent claims 38, 39, 44 and 45.

**v. No Proper Motivation to Combine the Denny and Edwards Patents**

The Examiner has also failed to establish a proper teaching, motivation, suggestion, or legitimate other reason, to combine the Denny and Edwards Patents to arrive at the claimed invention. See KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1742 (2007); In re Rouffet, 47 U.S.P.Q.2d 1453, 1456 (Fed. Cir. 1998). In particular, the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007). In this case, the Examiner has failed

to establish a proper teaching, suggestion, motivation, or other reason, to justify the combination of the Denny Patent and the Edwards Patents to arrive at the claimed invention because the combination fails to achieve the claimed invention, and the Taylor Patent fails to correct this deficiency.

Furthermore, the combination proposed by the Examiner is not obvious because the common sense of those of ordinary skill in the art would counsel against employing the device created by combining Denny and Edwards in the mouth of a wearer because the proposed combination fails to produce a “mouth and tongue stud” suitable for use in a wearer’s mouth.

**The Combination of Denny and Edwards Produces a Syringe and not a “Mouth and Tongue Stud”**

For all of the following reasons, the combination of Denny and Edwards produces a syringe, and not a “mouth and tongue stud” as claimed. Specifically, the Examiner states that

“the stud 103 [of Denny] was modified with the embodiment shown in Figures 4 [of Denny] to include the knob 406 disclosed by Denny at one end as the end member and the end member 50 taught by Edwards as the other end member. Therefore, the stud will be capable of remaining in the wearer’s mouth or lip” (Office Action, dated August 3, 2007, at 5, lines 14-18).

The Denny Patent discloses, in Figure 1, a syringe embodiment as discussed above. The Denny Patent discloses another syringe embodiment in Figure 4. The Examiner’s proposed combination of Figures 1 and 4 produces another syringe embodiment, albeit hypothetical, as shown in Figure A provided below. However, a conventional “mouth and tongue stud” is not a syringe. Likewise, a “mouth and tongue stud” in accordance with the present invention is not a syringe. Therefore, the Examiner has not shown a reasonable expectation of success of arriving at a “mouth and tongue stud,” once this term is properly construed in the light of Applicant’s specification, by combining the subject matter of the embodiments of Figures 1 and 4 of the Denny Patent. In re Vaeck, 20 U.S.P.Q.2d at 1442. In other words, the combination of embodiments of Figures 1 and 4 of the Denny Patent produces a syringe and not a “mouth and tongue stud.”

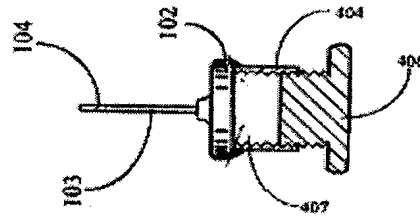


Figure A

The Edwards Patent discloses an earring that is a syringe. The Examiner's proposed combination of the subject matter of Denny and Edwards only results in another syringe such as shown in Figure B below. The combination of the Denny Patent and the Edwards Patent cannot produce a "mouth and tongue stud" as recited by the instant claims.

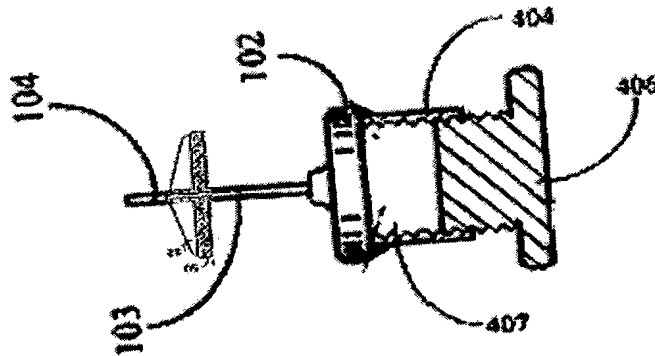


Figure B

In this case, while the Examiner should give the claimed term "mouth and tongue stud" the broadest reasonable interpretation consistent with Applicant's specification, In re Hyatt, 54 U.S.P.Q.2d at 1667, the Examiner's contention that a syringe, such as disclosed by the Denny Patent and the Edwards Patent, is a "mouth and tongue stud" is not a reasonable interpretation of this term. In particular, neither the conventional "mouth and tongue stud" nor the "mouth and tongue stud" of the present invention, as disclosed by Applicant's specification as originally filed, is a syringe. It is



not consistent with Applicant's specification to construe a "mouth and tongue stud" to include syringes. Therefore, because the proposed combination of Denny and Edwards produces a syringe, and not a "mouth and tongue stud," the Examiner has established no legitimate reason to combine the subject matter of these patents.

**The Syringe Produced by Denny and Edwards is Not Suitable for Use in the Mouth**

The syringe device resulting from the Examiner's proposed combination of Denny and Edwards is not suitable for use in the mouth for the following reasons. First, with reference to Figure B, the Examiner contends the device would include felt pad (50), (Office Action, dated August 3, 2007, at 5, lines 14-18). A person of ordinary skill in the art would instantly realize that felt is not a suitable material for use in the mouth.

Second, even if the Examiner were to combine Denny and Edwards so as to omit the felt pad (50) and employ only the friction retainer (52), a person of ordinary skill in the art would instantly realize that a friction retainer is still unsuitable for use in the mouth. Any man or woman who wears earrings would know that friction retainers frequently pop off and such earrings may be lost when worn in the earlobe even though the earlobe is a relatively fixed body part. The lips and tongue of the mouth, on the other hand, are very mobile and are frequently in motion when engaged in eating, speech and making facial expressions. Furthermore, the inside of the mouth is bathed in saliva, which is a lubricant. A person of ordinary skill in the art would instantly realize that a friction retainer (52), such as employed by Edwards, is unsuitable for use in the mouth because of the high risk that it will pop off the earring post. This is especially true because there is so much active movement in the mouth and the mouth is lubricated by saliva. Persons of ordinary skill in the art would be aware of the choking and aspiration hazard created by friction retainers if they were used in devices deployed in the mouth. Consequently, one does not see "mouth and tongue studs" that employ friction retainers. The use of a friction retainer (52), with or without the felt pad (50), would be contrary to the common sense knowledge of those of ordinary skill in the art.

Third, as shown by Figure B, the device resulting from the Examiner's combination of Denny and Edwards would have an exposed needle end (54). A person of ordinary skill in the art would instantly realize that such an exposed needle tip (54) would be unacceptable in a device worn in the mouth because it would be prone to injuring the soft tissue and mucosal lining of the mouth. In other words, the construction of a device, such as that resulting from the combination of Denny and Edwards proposed by the Examiner, for use in the mouth would be contrary to the common sense knowledge of a person of ordinary skill in the art.

Fourth, as shown by Figure B, the device resulting from the Examiner's combination of Denny and Edwards, would have knob (406) loosely threaded in base (404) when the reservoir (407) is full. A person of ordinary skill in the art would realize that, in the active environment of the mouth, the loose or partially threaded knob (406) may accidentally screw off of the base (404) altogether, thereby creating two problems. First, the knob (406), once detached from the base (404), becomes a choking and/or aspiration hazard. Second, the reservoir (407) will empty into the oral cavity and not into the piercing. Consequently, it would be contrary to the common sense knowledge of a person of ordinary skill in the art to employ an injection mechanism comprising knob (406) only loosely or partly threaded into base (404) in a device deployed in the mouth of a wearer. In other words, a person of ordinary skill in the art would know that threaded connections between parts of a "mouth and tongue stud" must be securely and snugly screwed together when deployed in the mouth of a wearer, and not loosely threaded as required to operate Denny's injection mechanism.

In sum, the hypothetical construct of Figure B, corresponding to the device resulting from the Examiner's proposed combination of Denny and Edwards, is not suitable for use as a "mouth and tongue stud" because (i) it employs a friction retainer, with or without a felt pad, which presents a choking and/or aspiration hazard, (ii) it has an exposed needle end, which is likely to injure the soft tissue and mucosal lining of the mouth, and (iii) its injection system employs the loosely threaded knob, which presents another choking and/or aspiration hazard.

The Examiner proposes a second hypothetical construct resulting from the combination of

Denny and Edwards, wherein

“the needle embodiment is being used with the reservoir 407 and knob 406 by combining the embodiments since the knob serves to dispense the substance and modifying the opposite end of the stud with the member with the end member 16 of Edwards that also serves to dispense a substance” (Office Action, at 6, lines 7-11).

The Examiner’s second hypothetical construct is illustrated below in Figure C. This hypothetical construct has two reservoirs, one on each end. Neither the Denny Patent nor the Edwards Patent teach, or even suggest, a double syringe as proposed by the Examiner. Therefore, the Examiner lacks a teaching, suggestion, motivation, or other legitimate reason, for picking and choosing parts from disparate disclosures and then recombining them as shown in Figure C. This dual reservoir, single

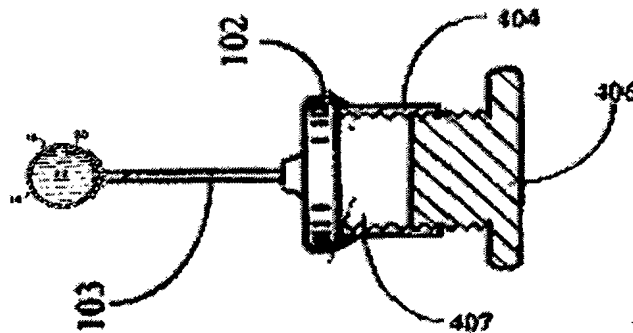


Figure C

needle hypothetical embodiment of the Examiner’s is also unsuitable for use in the mouth because its injection system employs the loosely threaded knob (406), which presents a choking and/or aspiration hazard. Furthermore, squeezable bulb (16) deployed at the other end of the injection system is unsuitable for use in the mouth because the mouth tissues will squeeze the bulb causing the bulb reservoir to be emptied almost immediately, thereby defeating the purpose of having a second reservoir. For all of the above reasons, the Examiner’s hypothetical construct as shown in Figure C fails to establish a prima facie case of obviousness because the combination of elements would be contrary to the common sense knowledge of a person of ordinary skill in the art.

For all of the above reasons, none of the hypothetical constructs resulting from the

combination of Denny and Edwards, as proposed by the Examiner, are suitable for use in the mouth of a wearer.

**The Examiner's "Official Notice"**

The Examiner contends that "there are topical antibiotics that are meant to be used orally when a user has an infection" (Office Action, dated August 3, 2007, at 6, lines 1-2). Applicant traverses the Examiners' apparent "Official Notice" and draws the Examiner's attention to Exhibit A, filed herewith, which demonstrates that topical antibiotics are for external use only.

The Examiner is reminded of her obligation under the Administrative Procedure Act to show the evidence on which her findings are based. In re Lee, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002). The Examiner cannot simply speculate or misread what the prior art teaches; instead, the Examiner must provide "substantial evidence support" for any Section 103 rejection. In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). In this case, not only has the Examiner failed to provide "substantial evidence support" for the contention that "there are topical antibiotics that are meant to be used orally when a user has an infection," Applicant has provided evidence to demonstrate that the Examiner's "Official Notice" is incorrect. Therefore, the Examiner must now produce "substantial evidentiary support" (i.e., a prior art reference) for the "Official Notice" or withdraw it.

In sum, none of the hypothetical constructs resulting from the combination of Denny and Edwards, as proposed by the Examiner, are suitable for use in the mouth of a wearer. As discussed above, the hypothetical constructs resulting from the combination of Denny and Edwards are syringes, and none of these devices is a "mouth and tongue stud" as this phrase should be construed in the light of Applicants' specification. The Examiner is reminded that the Federal Circuit has ruled that an Examiner cannot use improper hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. In re Fritch, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). There must be some teaching, suggestion, or incentive to make the combination made by the inventor – individual references cannot be employed as a mosaic to recreate a facsimile

of the claimed invention. Northern Telecom, Inc. v. Datapoint Corporation, 15 U.S.P.Q.2d 1321, 1323 (Fed. Cir. 1990). The fact that the combination of Denny and Edwards fails to produce a “mouth and tongue stud,” and the fact that the devices produced by the combination of Denny and Edwards are not even suitable for use in the mouth, demonstrates that the Examiner is employing hindsight reconstruction in an impermissible manner in this case.

For all of the above additional reasons, the Examiner has failed to establish a prima facie case of obviousness against independent claims 21, 31, 36 and 37.

The Examiner also cannot establish a prima facie case of obviousness against new independent claims 38, 39, 44 and 44 for the same reasons the Examiner has failed to establish a prima facie case of obviousness against independent claims 21, 31, 36 and 37.

### **III. CONCLUSION**

The Examiner has failed to establish a prima facie case of obviousness against independent claims 21, 31, 36 and 37 of the above-captioned application because neither the Denny Patent, the Edwards Patent nor the Taylor Patent teach, or even suggest, (i) a “mouth and tongue stud” and (ii) “the substance is dispensed into the wearer’s mouth by dissolving the substance over time in the wearer’s saliva” as recited in the independent claims. The Examiner has also failed to establish a proper motivation to justify the combination of the Denny Patent and the Edwards Patent because the subject matter of Edwards (e.g., needle conduit (30) with felt pad (50)), are not structures that a person of ordinary skill in the art would employ for intraoral use.

For all of the above reasons, claims 21-27, 31 and 36-47 are in condition for allowance and a prompt notice of allowance is earnestly solicited.

Questions are welcomed by the below-signed Applicant.

Respectfully submitted,

GRIFFIN & SZIPL, PC



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